IN THE UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF PENNSYLVANIA

MAUREEN PIEKANSKI

Plaintiff,

v.

ALEX AZAR II, in his official capacity as the Secretary of the Department of Health and Human Services.

Defendant.

Case No. 3:20-cv-00687

(Hon. Martin Carlson)

Electronically Filed

PLAINTIFF'S OBJECTIONS TO THE REPORT & RECOMMENDATION

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Dated: October 20, 2020

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Plaintiff, Mrs. Maureen Piekanski, appreciates Magistrate Judge Carlson's consideration of her motion for summary judgment and thanks him for his time. Mrs. Piekanski agrees with Judge Carlson's conclusions that Mrs. Piekanski has standing and that the Secretary's denial of Mrs. Piekanski's claim for coverage of her brain cancer treatment was not supported by substantial evidence.

That said, Mrs. Piekanski respectfully files these objections to the October 6, 2020 Report and Recommendation (hereinafter, "the Report") (Dkt. #63). In particular, Mrs. Piekanski objects to:

- 1) the failure to make a determination on the actual issue on which summary judgment was sought by both sides (collateral estoppel);
- 2) the determination that ALJ decisions granting coverage which became final after the ALJ Glaze' decision being appealed were not "relevant" and (partial) failure to consider them; and
- 3) the determination that Mrs. Piekanski's motion to strike and/or under FED.R.CIV.P. 56(d) is moot.

While both sides sought summary judgment on the issue of collateral estoppel, Judge Carlson did not actually issue a ruling on that issue. Instead, Judge Carlson issued a Report on an issue not briefed by other side – whether the ALJ's decision was supported by substantial evidence. Remanding this matter for further process focused on the merits subjects Mrs. Piekanski to the repeated litigation collateral estoppel exists to avoid. Further, a remand for further process focused on the merits denies Mrs. Piekanski the very relief sought by the Amended Complaint. *See* Dkt. #27 at 14 ("PRAYER FOR RELIEF - Enter an order: 1) finding that the Secretary

is collaterally estopped from relitigating whether TTFT treatment for Plaintiff is a covered benefit."). Accordingly, Mrs. Piekanski objects to the Report as neither addressing the issue on which summary judgment was sought nor granting Mrs. Piekanski the relief sought.

Assuming that this Court addresses the issue of collateral estoppel, then respectfully, Judge Carlson's determination that subsequent, final ALJ decisions (some of which are part of the administrative record) are not relevant is also in error. Subsequent, final ALJ decision are "judicial facts" and the long-standing rule is that judgments which become final (whether filed or decided before or after the non-final decision being appealed) may serve as the basis for collateral estoppel.

Again, assuming that this Court addresses the issue of collateral estoppel, then, respectfully, Mrs. Piekanski objects to Judge Carlson's conclusion that Mrs. Piekanski's motion to strike/under FED.R.CIV.P. 56(d) is moot. As set forth in Mrs. Piekanski's motion in this regard, absent the requested discovery, Mrs. Piekanski is precluded from challenging or rebutting the Secretary's claim that the volume of ALJ appeals makes it unfair to apply collateral estoppel. Thus, these portions of the Secretary's brief should be stricken or the discovery ordered and further briefing allowed.

I. BACKGROUND

As set forth in the Amended Complaint, Mrs. Piekanski is appealing a decision

by ALJ Glaze denying her claim for coverage of treatment (TTFT) for her brain cancer. Again, as set forth in the Amended Complaint, Mrs. Piekanski asserts that the Secretary is collaterally estopped from denying coverage based on prior and subsequent, final decisions finding that TTFT is medically reasonable and necessary for Mrs. Piekanski. The Amended Complaint seeks an outright determination that Mrs. Piekanski's claim is covered and a remand ordering coverage (*i.e.*, 42 U.S.C. § 405(g) fourth sentence).

In relevant part, on June 12, 2020, Mrs. Piekanski moved for summary judgment based on collateral estoppel. In particular, Mrs. Piekanski moved for summary judgment based on both prior and subsequent, final, ALJ decisions finding that TTFT was medically reasonable and necessary for Mrs. Piekanski and a Medicare covered treatment.

The Secretary was granted an extension of time to respond to Mrs. Piekanski's motion until July 13, 2020. On July 10, 2020, the Secretary moved to dismiss and for a stay, which Mrs. Piekanski subsequently opposed. Though no stay or dismissal was granted, the Secretary did not file an opposition to Mrs. Piekanski's motion on July 13, 2020. On August 7, 2020, Mrs. Piekanski filed a notice that the time for opposition had passed and that her motion could deemed unopposed. Thereafter, the Court issued an order requiring the Secretary to file an opposition to Mrs. Piekanski's motion for summary judgment by August 31, 2020 (*i.e.*, 80 days after

Mrs. Piekanski filed her motion).

On August 28, 2020, the Secretary both opposed Mrs. Piekanski's motion for summary judgment and filed a cross-motion for summary judgment. The Secretary's opposition and cross-motion contended broadly that applying collateral estoppel against the Secretary would be unfair; the elements of collateral estoppel were not met; and, improperly conflating precedence and collateral estoppel, that Medicare regulations (not a congressional directive) indicate that ALJ decisions are not precedential. Dkt. #50 at 2-3, 24-27; 13-15.

In order to counter the non-record evidence relied upon by the Secretary, Mrs. Piekanski served a FED.R.CIV.P. 30(b)(6) deposition notice seeking information on the number of ALJ appeals where the beneficiary was represented. The Secretary then moved for a protective order contending that the Secretary could offer non-record evidence but that Mrs. Piekanski was precluded from challenging it. On September 9, 2020, the Court issued an order stating: "discovery shall be stayed pending resolution of the outstanding dispositive motions in this case[.]" *See* Dkt. #55. Thus, Mrs. Piekanski was prevented from gathering the evidence needed to challenge and rebut the Secretary's non-record evidence.

In light of Mrs. Piekanski's inability to challenge or rebut the non-record evidence of ALJ appeals relied on by the Secretary, on September 18, 2020, Mrs. Piekanski moved to strike those portions of the Secretary's brief relying on the same

and/or to stay ruling on the Secretary's cross-motion for summary judgment until the discovery was made available under FED.R.CIV.P. 56(d). See Dkt. #58-1.

Also, on September 18, 2020, Mrs. Piekanski filed a reply in support of her motion for summary judgment.

II. DISCUSSION

A. This Court Should Address Collateral Estoppel and Award Mrs. Piekanski the Relief Sought

As set forth in the Amended Complaint, Mrs. Piekanski has been forced to repeatedly litigate the issue of whether TTFT is medically reasonable and necessary and a Medicare covered benefit for her, with inexplicably conflicting results. As set forth in the Amended Complaint and Mrs. Piekanski's motion for summary judgment, the primary goal of this suit is bring the repeated merits litigation to an end, both for herself and for others in the same situation. With the help of TTFT, a diagnosis of GBM should not be a death sentence and it also should not be a sentence to terminal litigation.

Thus, remanding this matter for further merits process (as the Report suggests) simply repeats the cycle of repetitious litigation that collateral estoppel exists to avoid (with the very inconsistencies noted in the Report). Mrs. Piekanski respectfully requests a ruling on her motion for summary judgment so that further merits litigation can be avoided and she can spend whatever remaining time she may have without a cloud of litigation hanging over her head.

As set forth in Mrs. Piekanski's moving papers, a presumption of the application of collateral estoppel exists in this context and the Secretary has not carried his burden of rebutting that presumption. While the Report notes that "changed circumstances" can defeat the application of collateral estoppel, the Report does not conclude that any are present in this case and there is no evidence of "changed circumstances." As the Report repeatedly notes, the same patient, with the same medical records, with the same diagnosis, and the same treatment plan, has received conflicting decisions as to whether the she is "newly diagnosed" or "recurrent", whether TTFT is "medically reasonable and necessary", and whether it is a Medicare covered benefit for her. Collateral estoppel exists to prevent precisely this result.

Respectfully, the Report's citation to disability caselaw (*see* Dkt. #53 at 31-33) is inapposite and merely an illustration of the uncontested principle that new evidence/changed circumstances can preclude the application of collateral estoppel. *See, e.g., Scooper Dooper, Inc. v. Kraftco Corp.*, 494 F.2d 840, 846 (3d Cir. 1974) (noting that changed factual circumstances can operate to preclude collateral estoppel).

For instance, the Third Circuit adjudicated a social security disability case in which a petitioner argued that an ALJ's findings regarding his functional status should be limited to those of a prior ALJ pursuant to res judicata. *Carter v. Barnhart*,

133 Fed. App'x. 33, 35 (3d Cir. 2005). In affirming that res judicata did not bind an ALJ's determination of a petitioner's functional capacity in a subsequent case, the court cited "new evidence" of the onset of diabetes mellitus that was unavailable to the prior ALJ. *Id.* The court also noted that the fact that the denied application dealt with a completely new date of disability, four years after the original application period, also contributed to the holding. *Id.* Similarly, in *Clark v. Barnhart*, the Third Circuit concluded that a disability determination six years prior did not bind a subsequent ALJ in 2002 in the review of a new application. 206 Fed. App'x. 211, 215 (3d Cir. 2006). Of course, the passage of six years when "there are no guidelines that provide once a claimant proves he is eligible for benefits, he will always be eligible for benefits" contributed to the finding. *Id.* That is, the fact that the applicant was disabled in 1996 did not necessarily reflect that he was disabled in the twelvemonth period before his new application was filed six years later. The Report cited a similar fact pattern as described in Zavilla v. Astrue, Civ. Action No. 09-133 2009 WL 3364853 (W.D. Pa. Oct. 16, 2009) (the passage of four years suggested that res judicata should not apply to bind an ALJ in a 2006 application for benefits following a distinct 2002 review of an initial application for benefits). In each of these cases, potential changed circumstances over long periods of time in the review of distinct applications for disability precluded the application of collateral estoppel.

The facts of Mrs. Piekanski's case are easily distinguished. Here, there are no

changed circumstances present between the records of ALJs Gulin and Glaze that would justify not applying collateral estoppel. As noted in the Report, even among themselves, Glaze #1 and #2 are characterized by "internal inconsistencies," "the research, *medical evidence*, and clinical studies that ALJ Glaze cited in September were available in January of 2019 when his first decision was issued, and were, in fact, cited in ALJ Gulin's decision which had been issued in November of 2018" (emphasis supplied). Dkt. #63 at 35.

In other words, the medical records before Judge Glaze were included in the record before Judge Gulin (and the same as those before Judge Glaze for his subsequent September decision finding coverage); there was no new evidence for Judge Glaze to consider that would justify a defense of changed circumstances. Moreover, the dates of service before Judge Glaze (December 2017 – February 2018) were immediately following the dates before Judge Gulin (September – November 2017), and there was no evidence of "changed circumstances" in the one month time difference, much less an explanation of the conflicting decisions in Glaze #2, Soulikias, and Myles.

Ultimately, Mrs. Piekanski's status as newly diagnosed or recurrent is irrelevant and Mrs. Piekanski highlights it only to demonstrate the internal inconsistencies among the various decisions. The Local Coverage Determination applicable at the time provided for blanket non-coverage of the device for all GBM

patients, regardless of characterization. *See e.g.*, Gulin Decision, A.R. 2469. In order for "changed circumstances" to apply, the "changed circumstances" must be material to the underlying conclusion and there is no evidence that "newly diagnosed" or "recurrent" was/is material to the issue of coverage.

At base, the caselaw cited in the Report cannot overcome the holdings of the Supreme Court with regard to the presumption of collateral estoppel. While there may not be a Third Circuit case that holds collateral estoppel applies in the Medicare context (Dkt. #63 at 31), the Supreme Court has articulated that there is a presumption that it does apply in these administrative circumstances, absent changed circumstances (which are not present in this case).

Finally, here, Mrs. Piekanski meets the required elements of collateral estoppel. As established in her Motion for Summary Judgment, the issues sought to be precluded in ALJ Glaze's case are the same as those involved in the prior (and subsequent) final actions (*i.e.*, whether TTFT is reasonable and necessary for Mrs. Piekanski and a Medicare covered benefit for her); the issues in the prior action were actually litigated; the issues in the previous actions were determined by valid and final judgments; and the determinations were essential to the prior judgments (*i.e.*, a finding of reasonableness and necessity is essential to determining that a service is a Medicare covered benefit). *See, e.g.*, Dkt. #28-15 at 16-21; Dkt. #57 at 11-15.

Importantly, the Report does not explicitly reject the application of collateral

estoppel in this context. Indeed, the Report repeatedly employs language that tracks the crux of collateral estoppel. Specifically, at various points, the Report states:

- -"...it is impossible to ignore the fact that the claims in this case all involve the same TTFT services (albeit over different dates), provided to the same beneficiary, in response to the same diagnosis." (Dkt. #63 at 4);
- -"ALJ Glaze was selected to review claims that involved the very same diagnosis, the same beneficiary, and the same resulting treatment..." (Dkt. #63 at 5);
- -"We cannot help but note the curious shift that occurred in the approximately nine months between ALJ Glaze's two contradictory opinions that concerned the same beneficiary, the same treatment plan, and the same treatments provided." (Dkt. #63 at 12);
- -"Perhaps more confusing is the fact that the research, medical evidence, and clinical studies that ALJ Glaze cited in September were available in January of 2019 when his first decision issued, and were, in fact, cited in ALJ Gulin's decision which had been issued in November 2018." (Dkt. #63 at 35).

Even though the Report declined to reach the issue of whether collateral estoppel bars the Secretary from denying Mrs. Piekanski's claim in this case, the Report nonetheless reiterated the exact point that Mrs. Piekanski is arguing: that the Secretary is continuing to deny claims for the same beneficiary for the same device for the same illness, when the Secretary has previously found that exact device for that exact beneficiary to be a Medicare covered benefit, thus creating inconsistency.

In sum, this Court should grant Mrs. Piekanski's Motion for Summary Judgment on the basis of collateral estoppel as the Supreme Court has held that it is

presumed to apply in the administrative context absent Congressional intent to the contrary. There is no cited caselaw or statute to overcome this presumption. Moreover, the elements of collateral estoppel have been met in Mrs. Piekanski's case.

B. Subsequent, Final ALJ Decisions Are Relevant to Collateral Estoppel

The Report concludes that only ALJ Gulin's decision of November 7, 2018, (finding that Mrs. Piekanski was "newly diagnosed" and awarding coverage) and ALJ Glaze' decision of January 18, 2019 – *i.e.*, "Glaze #1" - (finding that Mrs. Piekanski was "recurrent" and denying coverage) "are relevant to this appeal." *See* Report at 8, n. 2. That said, the Report makes multiple references to ALJ Glaze' later decision of September 13, 2019 – *i.e.*, "Glaze #2" - (finding that Mrs. Piekanski was "newly diagnosed" and awarding coverage) as "casting doubt" on ALJ Glaze's earlier decision. *See* Report at 11-13, 35. Respectfully, Mrs. Piekanski asserts that all five ALJ's decisions (Gulin, Glaze #1, Soulikias, Glaze #2, and Myles) at issue in this case are relevant and properly considered in determining this appeal. Thus, Mrs. Piekanski objects to the Report's conclusion that only the first two decisions are relevant.

As an initial matter, there is no dispute that the Gulin, Glaze #1, Soulikias, and Glaze #2 decisions are part of the administrative record in this case. *See* CAR 2461-2470 (Gulin), 2568-2578 (Glaze #1), 2471-2485 (Soulikias), 2486-2495

(Glaze #2). While ALJ Glaze had only the Gulin decision before him, Mrs. Piekanski supplied the Glaze #2 and Soulikias' decisions to the Medicare Appeals Council in support of her argument that the Secretary was bound by collateral estoppel. All of the decisions are relevant to the issue of collateral estoppel, as well as the other issues in this case (as Judge Carlson apparently found with respect to Glaze #2). Thus, all of those decisions are part of the administrative record in this case, they are relevant to, at least, the issue of collateral estoppel, and the Court may rely on them. *See* 42 U.S.C. § 405(g) ("a certified transcript of the record"; "The court shall have the power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision").

Further, as set forth in Mrs. Piekanski's motion for summary judgment, because of the nature of collateral estoppel, a later issued decision that becomes final may have preclusive effect on an earlier issued, but non-final, decision. *See* Dkt. #28-15 at 3. Thus, independent of their inclusion in the administrative record, this Court may take notice of the "judicial fact" of the subsequent decisions of Glaze #2, Soulikias, and Myles, regardless of whether they were before the agency at the time Glaze #1 issued or thereafter. *See Opoka v. INS*, 94 F.3d 392, 394-95 (7th Cir. 1996) ("derelict" in duty to not consider later issued decision). Again, each of Glaze #2, Soulikias, and Myles' decisions are relevant to, at least, the issue of collateral estoppel as they form at least some of the basis on which collateral estoppel may be

based.

Accordingly, these decisions are relevant and the Court should consider them.

C. Mrs. Piekanski's Motion to Strike/FED.R.CIV.P. 56(d) Is Not Moot

Because Judge Carlson did not rule on the issue on which summary judgment was sought (collateral estoppel) and independently found that ALJ Glaze' decision was not supported by substantial evidence, Mrs. Piekanski understands that Judge Carlson felt no need to address this discovery issue.

Nevertheless, on the assumption that this Court takes up the summary judgment issue, then Mrs. Piekanski's motion to strike and/or for relief under FED.R.CIV.P. 56(d) is not moot. The Secretary contends that applying collateral estoppel would be "unfair" should not apply because "it would not be practicable for the Secretary to defend himself in thousands of ALJ appeals filed each year." *See* Dkt. #50 at 29. In support of this claim, the Secretary relied, *inter alia*, on non-record evidence of a declaration filed by the Secretary in another case and the Secretary's publications in the FEDERAL REGISTER.

While Mrs. Piekanski disputes the Secretary's claim as a matter of law, Mrs. Piekanski also disputes the factual basis of the Secretary's claim. Pursuant to 42 CFR §§ 405.1012; 405.1018; 405.1036, if a beneficiary is NOT represented, then the Secretary may not appear as a party, cross-examine witnesses, etc. Thus, in order to rebut the Secretary's argument, Mrs. Piekanski needs evidence of how many ALJ

appeals there are each year where the beneficiary IS represented and that information is solely in the Secretary's possession.

Judge Carlson having precluded Mrs. Piekanski from gathering the evidence to rebut the Secretary's claim (*see* Dkt. #55), Mrs. Piekanski asks that either those portions of the Secretary's brief relying on the evidence be stricken or that Mrs. Piekanski be given the opportunity to discover the rebuttal evidence.¹

III. CONCLUSION

For the reasons set forth above, and those set forth at length in Mrs. Piekanski's Amended Complaint, Motion for Summary Judgment, and Motion to Strike, Mrs. Piekanski respectfully objects to the Report of Magistrate Judge Carlson, and requests the Court Grant her Motion for Summary Judgment in its entirety.

Respectfully submitted,

<u>/s/ Mark W. Fidanza</u>

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¹ The identical issue and arguments have been presented to two other courts and both have ordered the information produced by the Secretary. *See Wilmoth v. Azar*, Case No. 20-Civ-00120-NBB-RP (N.D. Miss. 2020) (discovery due by Oct. 23, 2020); *Thumann v. Azar*, Case No. 20-Civ-00125-TSB (S.D. Ohio 2020) ("Minute Entry and Notation Order" entered on docket on October 19, 2020 requiring discovery due by Oct. 26, 2020).

Attorneys for Plaintiff Maureen Piekanski

Dated: October 20, 2020

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CERTIFICATE OF SERVICE

I, Mark W. Fidanza, certify that a true and correct copy of the foregoing

Plaintiff's Objections to the Report and Recommendation was filed electronically

on October 20, 2020, is available for viewing and downloading from the federal

court's ECF/CM system, and will by automatically served upon registered counsel

of record by ECF/CM.

/s/ Mark Fidanza

Mark Fidanza